


Parent Project Muscular Dystrophy



Leading the Duchenne muscular dystrophy community

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HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

March 2, 2007

Re: Docket #2006D-0336 and Docket #2006D-0347

To Whom It May Concern:

The Parent Project Muscular Dystrophy (PPMD) is writing to express concern with FDA's draft guidance on ASRs and IVDMIAs (Docket #2006D-0336 and Docket #2006D-0347).

PPMD is dedicated to improving treatments for those affected with Duchenne muscular dystrophy (DMD), enhancing their quality of life and supporting promising research on this genetic disorder. DMD is the most common form of the more than 20 existing genetic disorders identified as muscular dystrophy. We believe that both draft guidances, if implemented as written, could slow or impede genetic research on DMD.

The importance of research and development with regard to DMD cannot be overestimated. Pioneering laboratories conducting new tests and experimenting with new technologies are on the forefront of personalized medicine in the 21st Century. With that in mind we are particularly concerned that if implemented, these guidances could impede patients' access to vital genetic testing. With specific respect to IVDMIAs, important medical tests could become unavailable or get mired in their current state of development. PPMD believes the issues at the heart of this matter are availability, access, affordability, and innovation. We believe the current drafts jeopardize each of these virtues.

Moving forward we respectfully request that FDA withdraw the draft guidance documents and undertakes a formal rule-making process. We have great respect for FDA and the regulatory protection it affords patients. We ask that you take into consideration PPMD's concerns with respect to both guidance documents.

We look forward to working collaboratively to ensure groundbreaking genetic tests can continue to improve and save lives.

Sincerely,



Patricia A. Furlong
President and CEO
Parent Project Muscular Dystrophy